

REMARKS**A. Status of the Claims**

Currently, claims 1-104 are pending. Of these claims, claims 2-23, 30, 31, 36-67, 73, and 76-98 have been withdrawn by the Examiner.

Applicants respectfully disagree with the Examiner's withdrawal of claims 30, 31 and 73. Applicants respectfully remind the Examiner that the election of species for prosecution on the merits only applies if no generic claim is finally held to be allowable. In other words, upon examination of the elected species and allowance of a generic claim, applicants are entitled to consideration of claims to additional species which otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. §1.141. Accordingly, should the Examiner's search of the elected "species" be unsuccessful in finding prior art, then applicants respectfully request the Examiner continue searching the non-elected species, including but not limited to those recited by claims 30, 31 and 73.

Claims 1, 24-29, 32-35, 68-72, 74, 75, and 99-104 are under examination.

Claims 34-35, 68-72, 74-75 and 99-104 have been rejected under 35 U.S.C. §112, ¶2 for allegedly being indefinite for failing to point out and distinctly claim the subject matter Applicant regards as the invention. Additionally, claims 1, 24-29, 32-35, 68-72, 74-75, and 99-104 have been rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over U.S. Patent No. 6,583,299 to Petrus ("Petrus"), in view of U.S. Patent No. 5,866,142 to Riordan ("Riordan") and U.S. Patent No. 6,113,636 to Ogle ("Ogle").

By this paper, Applicants have amended claims 1, 24, 29, 34, 35, 68, 72, 99, 100 and 103 and added claims 105-114. Support for new claims 105-114 are found throughout the application as originally filed, for example, as follows:

Claim 105: Specification, page 11, ¶36,

Claim 106: Specification, page 8, ¶22,

Claim 107: Specification, page 12, ¶38,

Claim 108: Specification, page 11, ¶36,

Claims 109-113: Specification, pages 9-10, ¶29, and

Claim 114: Specification, page 10, ¶33.

No new matter is introduced. Entry is respectfully requested.

B. Claim for Priority Under 35 U.S.C. §119(e).

Applicants thank the Examiner's consideration of Applicants' claim for priority under 35 U.S.C. §119(e) to U.S. Provisional Applications 60/421,278 and 60/421,336 and the properly granted priority date of October 25, 2002.

C. Response to the Rejections Under 35 U.S.C. §112, ¶2.

The Office Action of February 15, 2006 (hereafter "the Office Action") sets forth the following two grounds for rejecting Applicants' claims under 35 U.S.C. §112, ¶2 as rendering the claims indefinite: (1) use of the words "from" and "about" in claims 34-35 and 99-101, and (2) use of the phrase "providing in the vicinity of the lens one or more zinc-containing

components” in claim 68 and its corresponding dependent claims. Each of these rejections will be addressed in turn.

1. The Use of the Words “From” and “About”

According to the Office Action, the use of the words “from” and “about” render claims 34, 35, and 99-101 indefinite. In this response, Applicants have amended claims 34, 35, and 99 by deleting the word “from”, thereby rendering this rejection moot. The deletion of the word “from” does not change the scope of these claims nor the extent of the claimed ranges.

With respect to the word “about”, the Office Action notes that “[t]he expression ‘about’ is not defined by the claim, [and] the specification does not provide a standard for ascertaining the requisite degree, and thus one of ordinary skill in the art would not reasonably be apprised of the scope of the invention.”

Applicants respectfully disagree. It is well established that the term “about” when used to describe claimed ranges, as here, does not render the claims indefinite. See MPEP §2173.05(b). For example, in W.L. Gore & Assocs., Inc. v. Garlock, Inc., 721 F.2d 1540, (Fed. Cir. 1983), the Federal Circuit held that the “[t]he descriptive term ‘about’, which is used to explain the claimed ranges in the patents in suit, does not render a claim indefinite under 35 U.S.C. § 112”. Gore, 721 F.2d. at 1557. See also Ex parte Eastwood, 163 U.S.P.Q. 316, 317 (C.C.P.A. 168) (holding that “‘about’ is not broad or arbitrary but rather is a flexible term with a meaning similar to ‘approximately’”). Applicants’ specification provides those skilled in the art with a reasonable guidance regarding the meaning of the term “about”. For example, concentrations of 10.0 μ M Zn, 1.0 mM Zn and 100 mM Zn, which differ from each other by two orders of magnitude are referred to as “low”, “med” and “high”. Table 1 ¶54. In addition,

analysis of data is conducted at the 95% confidence level throughout the application which would imply a sufficient level of certainty in the concentrations used to obtain the data to be analyzed at the 95% confidence level.

For at least these reasons, Applicants respectfully assert that the term “about” does not render claims 34-35 and 99-101 indefinite. Reconsideration and withdrawal of the rejection of these claims under this ground of rejection are respectfully requested.

2. The Use of the Phrase “Providing in the Vicinity of...”

The Examiner contends that the phrase “providing in the vicinity of the lens one or more zinc-containing components” as recited in claim 68 and corresponding dependent claims renders these claims indefinite. The Examiner cites MPEP §2111, which states that “[d]uring patent examination, the pending claims must be given their broadest reasonable interpretation consistent with the specification”. The Examiner further contends that extremely broad interpretations are possible, because the specification and claims allegedly fail to provide any limitation to the phrase “in the vicinity of the lens”:

in the present case, the specification, nor the claims, provide any direction as to what would be considered to be inside or outside the vicinity of the lens. For these reasons, the term is given its broadest, reasonable interpretation. For example, it would not be outside the scope of the skilled artisan to interpret such a phrase to mean providing the zinc-containing components on or near the eyelid of the individual receiving such a therapy. However, an equally reasonable interpretation would be providing such zinc-containing components on or near the patient's mouth, which would result in a distinctly different therapeutic effect in treating disorders of the eye than when the components are provided directly to the eyelid.

Applicants respectfully disagree, because the suggested interpretation of Applicants' claims is not the "broadest reasonable interpretation consistent with the specification" as required by MPEP §2111. Rather, it appears that the interpretation adopted by the Office Action is one that disregards the teachings of the specification. For example, paragraph [20] of the specification explains how under one possible embodiment the lens of the eye can be treated with Applicants' inventive zinc-containing compositions. According to paragraph [20],

Yet another aspect of the invention comprises a method for increasing elastin content of the lens of an eye of a subject comprising placing over the lens a contact lens comprising one or more zinc-containing components, whereby the contact lens releases zinc ions onto the locus of the lens of the eye and/or adjacent tissues (such as muscles) in an effective elastin-increasing amount.

Furthermore, paragraph [41] states, *inter alia*, that

the contact lens would produce transient reshaping of the lens of the eye, and the ionic zinc would induce elastin production in that lens to confer elasticity for the corrected shape. The lens of the eye would tend to retain the corrected shape even after removal of the contact lens.

Thus, the Examiner's statement that providing zinc-containing components "on or near the patient's mouth" could be read as by a skilled artisan as "in the vicinity of the lens" is unfounded in view of the teachings of the specification. One of ordinary skill in the art would have a clear understanding of the metes and bounds of the claimed invention after reading Applicant's specification and claims.

Reconsideration and withdrawal of the rejection of claims 34-35, 68-72, 74, 75 and 99-101 under 35 U.S.C. §112, ¶2 are respectfully requested.

D. Response to the Rejections Under 35 U.S.C. §103(a)

Applicants respectfully traverse the rejection of claims 1, 24-29, 32-35, 68-72, 74-75, and 99-104 under 35 U.S.C. §103(a) for allegedly being unpatentable over Petrus, in view of Riordan and Ogle. The traversal is based on two grounds: (1) the combination is based on impermissible hindsight reconstruction, and (2) Riordan teaches away from the proposed combination. See MPEP §§ 2145(X)(A) and 2145(X)(D).

1. The Combination of References is Based on Impermissible Hindsight Reconstruction

According to the Examiner, Petrus teaches all of the claimed subject matter except for

- (1) the increase in elastin content of the tissue
- (2) the application of the zinc compound to the breasts, buttocks, neck, legs, arms, torso, and furrows or wrinkles in the hands or neck
- (3) the application of the zinc compound directly to the eye via a contact lens coated in the zinc-compound and
- (4) the claimed effective amounts of the zinc compound.

See Office Action at page 12.

The Examiner concedes that “Petrus does not expressly teach that topical application of the disclosed active composition increases elastin content in the tissue.” [Office Action, at page 12]. Nevertheless, the Examiner contends that “the very fact that the composition is used for improvement of dry skin and wrinkles as occurs with aging raises the reasonable expectation that such a treatment would necessarily have an effect on the elasticity of

the skin, since wrinkles due to aging were known to result from a loss of elastin” [Office Action at page 12]. To support these statements, the Examiner cites Riordan at col. 2, lines 18-34:

One of the mechanisms of the loss of elasticity in aging skin is through the loss of elastin, a human protein which is a major component in elastic fibers and provides skin with much of its elastic qualities....When the elastin molecules break down, they are removed by endogenous immune surveillance mechanisms and may not be replaced at the same rate, resulting in a net loss of elastin in the skin tissue. At the area at the lateral folds of the eyes, the forehead, and on the neck, the chronic net loss of elastin allows for the formation of wrinkles [Office Action pp. 12-13].

However, Applicants respectfully note that Riordan does not limit the wrinkling process to the loss of elastin. For example, Riordan explains that “[t]he aging process of the skin has been characterized by two main factors, the loss of elasticity and the loss of moisture” [Riordan, col. 1, lines 22-23 (emphasis added)]. The portion of Riordan relied on by the Examiner itself clearly acknowledges that loss of elastin is but one of the mechanisms for aging of skin. Moreover, nowhere does Riordan mention zinc in *any* form. Based on these two observations, one cannot not conclude *a priori* that the combination of Riordan and Petrus teaches the use of zinc to treat wrinkles by increasing elastin, unless one were to use improper hindsight reconstruction. Applicants further note that Ogle does not alleviate the deficiencies in the proposed combination of Petrus and Riordan, because Ogle only refers to the use of zinc for antimicrobial purposes, not for increasing elastin [see, e.g., Ogle, col. 4, lines 18-20].

In sum, the proposed combination of Petrus with Riordan is the product of impermissible hindsight reconstruction based on Applicants’ own invention. For at least this reason, the rejections of Applicants’ claims under 35 U.S.C. §103(a) over Petrus in view of Riordan and Ogle should be withdrawn.

2. Riordan Teaches Away from the Proposed Combination

In attempting to arrive at Applicants' invention, the Examiner tries to combine the teaching of Petrus regarding the topical application of zinc compounds with an alleged teaching in Riordan that wrinkles occur because of elastin degradation. However, in doing so, the Examiner neglects an important aspect of Riordan: Riordan is directed to preventing wrinkles by eliminating divalent cations in the skin by using divalent cation chelators, such as histidine or EDTA. This is significant because zinc, as found in zinc citrate, is also a divalent cation. There is no teaching in Riordan that some divalent cations (viz. zinc) should be allowed to remain in the skin because they could be beneficial. Moreover, it is well established that Zn(EDTA) complexes are known. Thus, based on the complete teachings of Riordan, one of ordinary skill in the art would seek to remove divalent cations (e.g., zinc) from the skin, rather than adding them to the skin. Thus, Riordan teaches away from the proposed combination. As before, Ogle does not alleviate the deficiencies of the proposed combination. At best, Ogle merely mentions that Zn can be used for antimicrobial purposes [Ogle, col. 4, lines 18-20].

Based on the above, the rejection of Applicants' claims under 35 U.S.C. §103(a) should be withdrawn. Applicants respectfully request reconsideration and withdrawal of the rejection of these claims over Petrus, in view of Riordan and Ogle.

CONCLUSION

Based on the foregoing amendments and remarks, Applicants respectfully request reconsideration and withdrawal of the rejection of claims and allowance of this application.

AUTHORIZATION

The Commissioner is hereby authorized to charge any additional fees which may be required for consideration of this Amendment to Deposit Account No. **13-4500**, Order No. 4649-4014US1. A DUPLICATE OF THIS DOCUMENT IS ATTACHED.

In the event that an extension of time is required, or which may be required in addition to that requested in a petition for an extension of time, the Commissioner is requested to grant a petition for that extension of time which is required to make this response timely and is hereby authorized to charge any fee for such an extension of time or credit any overpayment for an extension of time to Deposit Account No. **13-4500**, Order No. 4649-4014US1. A DUPLICATE OF THIS DOCUMENT IS ATTACHED.

Respectfully submitted,
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